

K963375

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SUMMARY OF STATEMENT OF SAFETY AND EFFECTIVENESS

CardiacMonitor - Cardiac Event Recorder

L. A. Wood Electronics, Inc.

Ref: K963375

The CardiacMonitor is a non-invasive, external ambulatory electrocardiographic (ECG) looping memory monitor. The device is activated by the patient who experiences transient symptoms and is intended for human use, in the home or workplace. The recorded ECG is sent by an acoustic signal from an internal speaker, using standard telephone lines to a telephonic receiver. The CardiacMonitor is the size of a Credit-card by about 0.31" thick.

The device records either a 90 second ECG when Physician set in the (P.) mode or a 30 second pre-symptom and a 60 second post-symptom for a 90 second total ECG when Physician set in the (P.P.) mode. The function of the (P.) or (P.P.) mode have no impact on the quality of the ECG data obtained. The CardiacMonitor Shares much of the same operating features as the predicate device, HeartCard and the technical specifications comparison reveal no substantial differences and no differences which would effect safety and effectiveness. The indications for use are the same.

A leadset provides means for attachment to standard ECG electrodes. Moving the slide switch to the (P.P.) mode activates the ECG scanning operation, during which ECG data is being stored in a looping memory. The memory loop continues to fill with the most recent ECG data. When the RECORD button is activated, the looping memory content is in non-looping memory.

The data stored in memory may be sent by the patient to a receiving center. The patient calls the center and when instructed places the mouthpiece of the telephone over the yellow circle on the monitor and presses and releases the telephone mouthpiece. The ECG data is sent over the phone lines via an acoustic signal. The data may be sent again if requested. The stored data is retained until the "Erase" button is pressed.

AAMI EC-13 and EC-38 test data results are all within the minimum and maximum allowable standards and no impact on safety and effectiveness is shown.